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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,433	01/16/2002	Jian Ni	PF511P1	3443
22195	7590	12/04/2003	EXAMINER	
HUMAN GENOME SCIENCES INC			O HARA, EILEEN B	
9410 KEY WEST AVENUE			ART UNIT	
ROCKVILLE, MD 20850			PAPER NUMBER	
			1646	

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/046,433	<b>Applicant(s)</b> NI ET AL.	
	<b>Examiner</b> Eileen O'Hara	<b>Art Unit</b> 1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,7,10,13,16,19-21,23,28-30,34-38 and 64-131 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,7,10,13,16,19-21,23,28-30,34-38 and 64-131 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)      7/2/03
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_      2/10/03
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1, 4, 7, 10, 13, 16, 19-21, 23, 28-30, 34-38 and 64-131 are pending in the instant application. Claims 1, 20, 21 and 23 have been amended, claims 33, 40, 44 and 46 have been canceled in the Paper filed August 19, 2003.

All pending claims are currently under examination.

### ***Information Disclosure Statement***

2. The IDS filed February 10, 2003, has been corrected and a copy sent to Applicants, since reference AB was identified as Application 09/912,923, and Applicants have correctly identified it as Application 09/912,293 in the amendment filed August 19, 2003.

### ***Objection to Specification***

3. The objections to the specification are withdrawn in view of Applicants' amendment.

### ***Priority Statement***

4. Applicants' amendment to the specification to correct the priority date is acknowledged.

### ***Withdrawn Objections and Rejections***

5. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 20, 21, 23, 28-30, 34-38, 64, 65, 68, 71, 74-77, 80, 83, 86-105, 107, 109, 111, 113, 115 and 117-130 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record in the previous Office Action, Paper No. 8, at pages 9-11, and below.

Applicants traverse the rejection and assert that in an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability, and that the Examiner has not meet this burden. Applicants cite *in re Wertheim*, *Amgen, Inc. v. Chugai Pharmaceutical Co.*, *Vas-Cath Inc. v. Muhurkar*, *Union Oil Company of California v. Atlantic Richfield Company* and *University of California v. Eli Lilly*, as support for their position that one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed, and that all of the objectives met by a generic chemical formula are similarly met by the explicit description in the instant specification of a polynucleotide sequence (SEQ ID NO: 39) and the amino acid sequence encoded thereby (SEQ ID NO: 40), various smaller fragments of the protein, and polypeptides having 95% percent identity to SEQ ID NO: 40. Applicants further argue that the instant claims clearly distinguish the boundaries of the claimed genera and identify

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all of the members of those genera, and that one skilled in the art would reasonably conclude that Applicants had possession of the polypeptides encompassed by the rejected claims upon reading the present application as filed, and has provided a description sufficient to allow the skilled artisan to readily envision the additions, deletions, and substitutions falling within the claims. Applicants' arguments have been fully considered but are not deemed persuasive. Under the Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, "Written Description", a representative species may be adequately described through its structure, through its functional characteristics, or through a combination of its structure and function. In the instant case the claims encompass polypeptides comprising portions of the full-length protein and/or polypeptides comprising portions at least 95% identical to portions of the full-length protein. Therefore, the rejection is maintained.

Why?  
You haven't  
given  
reasons!

### ***Priority***

7. Applicants traverse the determination of the priority date accorded the instant application, that of the filing date, Jan. 16, 2002, and assert that determination that an application is not supported by either a specific and substantial utility or a well established utility is improper when a person of ordinary skill in the art would find credible disclosed or characteristics of the invention, or states made by the application in the written description of the invention, and applicant need only make one credible assertion of utility for the claimed invention to satisfy 35 U.S.C. 101. Applicants further assert that finding a lack of utility is also improper if a person of ordinary skill in the art would know of a use for the claimed invention at the time the application was filed and moreover, that the burden is on the Examiner to establish why it is more likely than

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not that one of ordinary skill in the art would doubt the truth of the statement of utility, and that the Examiner must provide evidence sufficient to establish that a person of person of ordinary skill in the in the art would not believe the applicant's assertion of utility. Applicants assert that the Provisional application No. 60/144,087, filed July 16, 1999, teaches that TR13 is a novel member of the Tumor Necrosis Factor Receptor family of polypeptides, it is involved in the regulation of apoptosis, and that it is expressed in a number of tissue and cells types and specifically that it is found in resting and activated T-cells and well as apoptotic T-cells, and that the application provides compositions and methods of enhancing and inhibiting apoptosis, and teaches how these compositions may be useful in the treatment of specific diseases. Applicants further assert that the present application has provided experimental evidence that TR13 does regulate cell survival, serving to reduce fibroblast survival in a manner and to an extent comparable to the combination of Fas and FasL, and therefore these data merely serve to support the assertions of the '087 application.

Applicants' arguments have been fully considered but are not deemed persuasive. The '087 application states on page 5, lines 10-14:

Thus, the invention further provides a method for inhibiting apoptosis induced by a TNF-family ligand, which involves administering to a cell which expresses the TR13 polypeptide an effective amount of an agonist capable of increasing TR13 mediated signaling. Preferably, TR13 mediated signaling is increased to treat a disease wherein increased apoptosis is exhibited.

However, the present application teaches that administering an agonist (ligand) to a cell expressing the TR13 causes apoptosis, and does not inhibit it, as taught in the '087 application, so that the present application is not supported by the teachings of the '087 application.

Therefore, the priority determination is maintained.

***Claim Rejections - 35 USC §§ 102 and 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1, 4, 7, 10, 13, 16, 19-21, 23, 29-30, 34-38, 64, 65, 68, 71, 74, 75, 77, 80, 83, 86-96, 98-105, 107, 109, 111, 113, 115, 117-124, 126-130 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bruck et al., WO 00/58460, October 5, 2000.

Claims 1, 4, 7, 10, 13, 16, 19-21, 23, 28-30, 34-38 and 64-131 remain rejected under 35 U.S.C. 102(a) as being anticipated by Ruben et al., WO 01/05834, January 25, 2001.

Claims 97 and 125 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bruck et al., WO 00/58460, October 5, 2000, in view of Fleeer et al., PN 5,876,969.

Applicants traverse the rejections and assert that as the correct effective priority date of the present application is July 16, 1999, Bruck et al., Ruben et al. and Fleeer et al. do not qualify as prior art under 35 USC § 102 or § 103.

Applicants' arguments have been fully considered but are not deemed persuasive, because the effective priority date is considered Jan. 16, 2002, as discussed above under the priority determination, and the rejections are maintained.

It is believed that all pertinent arguments have been answered.

***Conclusion***

9. No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.



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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

A handwritten signature in cursive script, reading "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

**LORRAINE SPECTOR  
PRIMARY EXAMINER**